APR 2 7 2004

K033085

510(k) Summary
Cardio Life Research
Portaclamp™

1. SPONSOR

Cardio Life Research, s.a.
Rue De Clairvaux 40/203
B 1348 Louvain La Neuve
Belgium

Contact : Michel Joie
Phone: +32 10 480 492

Date Prepared: September 26, 2003

2. DEVICE NAME

Proprietary Name:	Portaclamp™
Common/Usual Name:	Aortic clamp
Classification Name:	Vascular clamp

3. PREDICATE DEVICES

- Cosgrove Vascular Clamp (K974769)
- Heartport Cable Bulldog Clamp (K962366)
- Heartport Endoaortic Clamp (K955132)

4. DEVICE DESCRIPTION

The Portaclamp™ is a disposable aortic clamping device that is designed to be used through a standard thoracic port to clamp the aorta during minimally invasive cardiac bypass procedures. The Portaclamp™ consists of a flexible guide wire, two jaws that are passed over the guide wire and positioned on each side of the aorta, and a mandrel that is slid along the length of the jaws to compress the jaws and clamp the aorta.

5. INTENDED USE

The Portaclamp™ is indicated to clamp the aorta during minimally invasive cardiac surgery implying the usage of an extra-corporeal circulation.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Portaclamp™System is substantially equivalent to other predicate vascular clamps that are used for aortic clamping during cardiac surgery. The Portaclamp™ and the predicate devices have fundamentally the same indications for use. All of these devices are designed to be used to temporarily clamp vessels during surgical procedures. such as the aorta during cardiac surgery.

7. PERFORMANCE TESTING

Information submitted in this premarket notification for the Portaclamp™ includes results of biocompatibility testing, in vitro performance testing, cadaver testing and clinical experience.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2004

Cardio Life Research, S.A.
c/o Mr. James R. Veale
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K033085
Portaclamp™ Aortic Clamp
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: March 2, 2004
Received: March 3, 2004

Dear Mr. Veale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lachman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K033085**

Device Name: **Portaclamp™**

Indications For Use:

The Portaclamp™ is indicated to clamp the aorta during minimally invasive cardiac surgery implying the usage of an extra-corporeal circulation.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vechinel

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033085